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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,117	08/30/2001	Andreas Menrad	SCH-1832	6934

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EXAMINER
HADDAD, MAHER M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,117	MENRAD ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2001 and 24 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant is reminded that "use" claims are non-statutory and are not appropriate for US practice (see MPEP 2173.05(q)).

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 1-16, drawn to a protein that has the ability to bind specifically to the ED_b-fibronectin domains and that has an apparent molecular weight of 120-130 kDa for the light chain and 150-160 kDa for the heavy chain, wherein the binding region comprises the $\alpha 2\beta 1$ chain of the integrin; classified in Class 530, subclass 395.

2. Claims 17-22, 24 and 42-45, drawn to an antibody that binds to a protein that has the ability to bind specifically to the ED_b-fibronectin domains or an antibody that binds to SEQ ID NO:1 and a method of producing; classified in Class 530, subclass 387.3.

3. Claims 18 and 42, drawn to an antibody that binds to SEQ ID NO:1 and a method of producing; classified in Class 530, subclass 387.3.

4. Claims 18 and 42, drawn to an antibody that binds to SEQ ID NO:2 and a method of producing; classified in Class 530, subclass 387.3.

5. Claims 18 and 42, drawn to an antibody that binds to SEQ ID NO:3 and a method of producing; classified in Class 530, subclass 387.3.

6. Claims 18 and 42, drawn to an antibody that binds to SEQ ID NO:4 and a method of producing; classified in Class 530, subclass 387.3.

7. Claim 23, drawn to a cell that expresses a protein of SEQ ID NO: 1, classified in Class 435, subclass 455.

8. Claim 25, drawn to a phage that expresses an antibody that able to bind to a protein that has the ability to bind specifically to the EDb-fibronectin domains; classified in Class 536, subclass 23.53.

9-13. Claims 26-28, and 31-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 1 comprises comparison of a response, wherein the response comprises the adherence of cells, classified in Class 435, subclasses 6 and 7.1.

14-18. Claims 26-28 and 31-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 2 comprises comparison of a response, wherein the response comprises the adherence of cells, classified in Class 435, subclasses 6 and 7.1.

19-23. Claims 26-28 and 31-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 3 comprises comparison of a response, wherein the response comprises the adherence of cells, classified in Class 435, subclasses 6 and 7.1.

24-28. Claims 26-28 and 31-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 4 comprises comparison of a response, wherein the response comprises the adherence of cells, classified in Class 435, subclasses 6 and 7.1.

29-33. Claims 26-27, 29 and 31-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 1 comprises comparison of a response, wherein the response comprises the proliferation of cells, classified in Class 435, subclasses 6 and 7.1.

34-38. Claims 26-27, 29 and 31-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 2 comprises comparison of a response, wherein the response comprises the proliferation of cells, classified in Class 435, subclasses 6 and 7.1.

39-43. Claims 26-27, 29 and 31-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind

to a receptor of the EDb-fibronectin domain of SEQ ID NO: 3 comprises comparison of a response, wherein the response comprises the proliferation of cells, classified in Class 435, subclasses 6 and 7.1.

44-48. Claims 26-27, 29 and 31-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 4 comprises comparison of a response, wherein the response comprises the proliferation of cells, classified in Class 435, subclasses 6 and 7.1.

49-53. Claims 26-27 and 30-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 1 comprises comparison of a response, wherein the response comprises the proliferation, migration and differentiation of endothelial cells, classified in Class 435, subclasses 6 and 7.1.

54-58. Claims 26-27 and 30-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 2 comprises comparison of a response, wherein the response comprises the proliferation, migration and differentiation of endothelial cells, classified in Class 435, subclasses 6 and 7.1.

59-63. Claims 26-27 and 30-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 3 comprises comparison of a response, wherein the response comprises the proliferation, migration and differentiation of endothelial cells, classified in Class 435, subclasses 6 and 7.1.

64-68. Claims 26-27 and 30-33, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 4 comprises comparison of a response, wherein the response comprises the proliferation, migration and differentiation of endothelial cells, classified in Class 435, subclasses 6 and 7.1.

69-73. Claims 34-35 and 38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 1 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the adherence of cells, classified in Class 435, subclasses 6 and 7.1.

74-78. Claims 34-35 and 38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers *respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 2 comprises comparison of a response in

the presence of different concentrations of the compound, wherein the response comprises the adherence of cells, classified in Class 435, subclasses 6 and 7.1.

79-83. Claims 34-35 and 38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 3 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the adherence of cells, classified in Class 435, subclasses 6 and 7.1.

84-88. Claims 34-35 and 38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 4 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the adherence of cells , classified in Class 435, subclasses 6 and 7.1.

99-103. Claims 34, 36 and 38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 1 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the proliferation of cells, classified in Class 435, subclasses 6 and 7.1.

104-108. Claims 34, 36 and 38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 2 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the proliferation of cells, classified in Class 435, subclasses 6 and 7.1.

109-113. Claims 34, 36 and 38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 3 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the proliferation of cells, classified in Class 435, subclasses 6 and 7.1.

114-118. Claims 34, 36 and 38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 4 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the proliferation of cells, classified in Class 435, subclasses 6 and 7.1.

119-123. Claims 34 and 37-38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 1 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises

the proliferation, migration and differentiation of endothelial cells, classified in Class 435, subclasses 6 and 7.1.

124-128. Claims 34 and 37-38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 2 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the proliferation, migration and differentiation of endothelial cells, classified in Class 435, subclasses 6 and 7.1.

129-133 Claims 34 and 37-38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 3 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the proliferation, migration and differentiation of endothelial cells, classified in Class 435, subclasses 6 and 7.1.

134-138. Claims 34 and 37-38, drawn to a process for screening **antibodies, peptides, low-molecular compounds, aptamers and Spiegelmers** ***respectively*** that bind to a receptor of the EDb-fibronectin domain of SEQ ID NO: 4 comprises comparison of a response in the presence of different concentrations of the compound, wherein the response comprises the proliferation, migration and differentiation of endothelial cells, classified in Class 435, subclasses 6 and 7.1.

139-142. Claim 39, drawn to a method for screening compounds using a **nucleic acid** that codes for a protein that comprises SEQ ID NO:1-4 **respectively** for screening compounds that bind to a receptor of the ED_b-fibronectin, classified in Class 435, subclass 6.

143-146. Claim 39, drawn to a method for screening compounds using a **nucleic acid** that codes for a protein that comprises SEQ ID NO:1-4 **respectively** for screening compounds that bind to the ED_b-fibronectin domains, classified in Class 435, subclass 6.

147-150. Claim 40, drawn to a method for screening compounds using **a protein** of SEQ ID NO:1-4 **respectively** for screening compounds that bind to a receptor of the ED_b-fibronectin, classified in Class 435, subclass 7.1.

151-154. Claim 40, drawn to a method for screening compounds using **a protein** of SEQ ID NO:1-4 **respectively** for screening compounds that bind to the ED_b-fibronectin domains, classified in Class 435, subclass 7.1.

155-158. Claim 41, drawn to a method for screening compounds using a cell expresses a protein of SEQ ID NO: 1-4 **respectively** that bind to a receptor of the ED_b-fibronectin, classified in Class 435, subclass 7.21.

159-162. Claim 41, drawn to a method for screening compounds using a cell expresses a protein of SEQ ID NO: 1-4 **respectively** that bind to the ED_b-fibronectin domains, classified in Class 435, subclass 7.21.

163-166. Claim 46, drawn to a method for a pro-angiogenic therapy using a protein of SEQ ID NO:1-4 **respectively**, classified in Class 514, subclass 2.

167-170. Claim 47, drawn to a method for diagnostic purposes using a protein of SEQ ID NO:1-4 **respectively**, classified in Class 435, subclass 7.1.

171-174. Claim 48, drawn to a method for a gene therapy using a nucleotide encoding SEQ ID NO:1-4 **respectively**, classified in Class 514, subclass 2.

175-178. Claims 49-50, drawn to a method for coating surfaces that binds to the endothelial cells *in vitro* using a protein of SEQ ID NO:1-4 **respectively**, classified in Class 514, subclass 2.

179-182. Claims 49-50, drawn to a method for coating surfaces that binds to the endothelial cells *in vivo* using a protein of SEQ ID NO:1-4 **respectively**, classified in Class 514, subclass 2.

183-186. Claim 51, drawn to a method of using a protein of SEQ ID NO:1-4 **respectively** in cell cultures, classified in Class 434, subclass 7.1.

187-190. Claim 52-53, drawn to a method of using a protein of SEQ ID NO:1-4 **respectively** in transplant, classified in Class 434, subclass 7.1.

191-194. Claim 54-55, drawn to a method of using a protein of SEQ ID NO:1-4 **respectively** in implant, classified in Class 434, subclass 7.1.

4. Groups 1-8 are different products. Proteins, and antibodies to the polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups 9-194 are different methods. A method of screening, a method of diagnostic, a method for coating, a method for pro-angiogenic therapy, and a method for gene therapy, differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups 2-6/9-138 are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of anyone of Groups 2-6 can be used for affinity purification, in addition to the methods of screening recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group 1 is elected, applicant is required to elect a protein that has the ability to bind specifically to the ED_b-fibronectin domains and that has an apparent molecular weight of 120-130 kDa for the light chain and 150-160 kDa for the heavy chain, wherein the binding region comprises the $\alpha 2\beta 1$ chain of the integrin, wherein the binding region is characterized by a sequence (such as SEQ ID NO: 1, SEQ ID NO:2 or SEQ ID NO:3). These sequences are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

B. If anyone of Groups 187-190 is elected, applicant is required to elect a method of using a protein of SEQ ID NO:1-4 **respectively** in transplant, wherein the transplant is specifically one of the transplants recited in claim 53. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

C. If anyone of Groups 191-194 is elected, applicant is required to elect a method of using a protein of SEQ ID NO:1-4 **respectively** in implant, wherein the implant is specifically one of the implants recited in claim 54. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 36 is generic.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
September 30, 2002

Christina Chan

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